UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,553	11/25/2003	Surinder K. Batra	UNMC.63121.1	6633

110 7590 05/05/2006

DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER	
GODDARD, LAURA B	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,553	BATRA ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *4/28/06* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The Amendment filed January 27, 2006 in response to the Office Action of October 25, 2005, is acknowledged and has been entered. Previously pending claims 28, 31 and 34 have been amended. Claims 28-36 are currently being examined.

Examiner acknowledges submission of a declaration under 37 C.F.R. 1.131 to establish conception and reduction to practice the claimed subject matter of the instant application prior to September 23, 1997 filing date of US Patent 5,932,442 to overcome the USC 102(b) and 103(a) rejections stated in the Office Action of October 25, 2005, p. 3-5.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action

Claim Objections

3. Claim 35 is objected to because of the following informalities: Claim 35 depends on the kit of claim 33 and there is no kit in claim 33. It appears Applicant intended to have claim 35 depend on claim 34 and application will be examined as such. Appropriate correction is required.

4. Claim 34 is objected to because of the following informalities: There appears to be a typographical error. The claim recites "PD2 protein for use a positive control" which should read as "PD2 protein for use **as** a positive control".

Rejection Maintained

Claim Rejections - 35 USC § 112

5. Claims 34-36 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of laboratory designations only to identify a particular protein or protein fragment such as PD2 renders the claims indefinite because different laboratories may use the same laboratory designation to define completely distinct proteins or protein fragments. For example, Sato et al (American Society of Plant Biologists, 1997, Abstract # 90) use the name PD2 to describe "a distant homolog of trans-Golgi (TGN) membrane protein. Immunoblotting and immunocytochemistry showed that PD2 is localized to chloroplast envelope but not nucleus," indicating a plant protein. Amendment of the claims are to include the **SEQ ID number** which unambiguously defines a given protein or protein fragment.

6. Applicants amended claims 28, 31, and 34 to define PD2 as a protein having the sequence of SEQ ID NO:2, however claims 34-36 are still rejected because claim 34 recites "**and optionally PD2 protein for use a positive control**". Amendment of the

claims to recite, for example, "**and optionally said PD2 protein for use as a positive control**" would obviate the rejection.

NEW REJECTIONS

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 28-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for **an antibody immunologically specific for an isolated human PD2 protein consisting of SEQ ID NO:2**, does not reasonably provide enablement for an antibody immunologically specific for an isolated human PD2 protein having the sequence of SEQ ID NO:2, wherein said human PD2 protein is about 531 amino acids in length. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed

invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to an antibody immunologically specific for an isolated human PD2 protein **having the sequence of** SEQ ID NO:2, wherein said human PD2 protein is **about** 531 amino acids in length, a kit comprising said antibody, and a method for detecting human PD2 having the sequence of SEQ ID NO:2 or a fragment thereof comprising using said antibody. The claims are broadly drawn to an antibody that binds to a protein **having the sequence of** SEQ ID NO:2 which means a protein **comprising** both SEQ ID NO:2 and any other unknown sequence, this means the antibody could bind to sequences on the PD2 protein that do not include SEQ ID NO:2.

The specification discloses that PD2 and antibodies that bind PD2 are novel biological molecules useful in the detection and or molecular characterization of components involved in the regulation of cellular differentiation and tumorigenesis (p. 3, lines 26-31). The specification discloses that human PD2 protein has the amino acid sequence of SEQ ID NO:2 (p. 5, lines 8-10; Fig. 2). The specification discloses that

antibodies immunologically specific for PD2 protein may be used to detect and quantitate PD2 protein and diagnose pancreatic cancer (p. 32, lines 26-29; p. 37, lines 27-30). The specification discloses that human PD2 is overexpressed in pancreatic cancer and is involved in the development of pancreatic cancer (Example I, p. 45; Example III, p. 53).

One cannot extrapolate the diclosureof the specification to the scope of the claims because the specification does not provide guidance or examples for making and using an antibody immunologically specific for SEQ ID NO:2 that binds to anything other than SEQ ID NO:2. Clearly one of skill in the art would not know how to use an antibody that binds to any other sequences other than SEQ ID NO:2. An antibody that binds to a protein having SEQ ID NO:2 is not required to bind to SEQ ID NO:2 and would not predictably function as claimed and contemplated.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be reasonably predicted that **an antibody** that binds to a protein having SEQ ID NO:2 will predictably function as broadly claimed and contemplated. Therefore, in view of the novel nature of the invention, the breadth of the claims, lack of guidance in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

8. Claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for detecting human PD2 protein having

the sequence of SEQ ID NO:2 in a sample comprising contacting a sample with the antibody as claimed in claim 28 or a kit for detecting human protein having the sequence of SEQ ID NO:2, does not reasonably provide enablement for a method for detecting human PD2 protein having the sequence of SEQ ID NO:2 **or a fragment thereof** in a sample comprising contacting a sample with the antibody as claimed in claim 28 or a kit for detecting human protein having the sequence of SEQ ID NO:2 **or a fragment thereof.** The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state

of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The claims are drawn to a method for detecting human PD2 protein having the sequence of SEQ ID NO:2 **or a fragment thereof** in a sample comprising contacting a sample with the antibody as claimed in claim 28 (claims 31-33)and a kit for detecting human protein having the sequence of SEQ ID NO:2 **or a fragment thereof** (claims 34-36). The claims are broadly drawn to a method of or a kit for detecting fragments of a protein that comprises SEQ ID NO:2 and/or other unknown sequences. A "human PD2 protein having the sequence of SEQ ID NO:2 or a fragment thereof" is broadly drawn to a protein comprising SEQ ID NO:2 and other unknown sequences, of which some of the fragments may comprise only the unknown sequences.

The specification discloses that PD2 and antibodies that bind PD2 are novel biological molecules useful in the detection and or molecular characterization of components involved in the regulation of cellular differentiation and tumorigenesis (p. 3, lines 26-31). The specification discloses that human PD2 protein has the amino acid sequence of SEQ ID NO:2 (p. 5, lines 8-10; Fig. 2). The specification discloses that antibodies immunologically specific for PD2 protein may be used to detect and quantitate PD2 protein and diagnose pancreatic cancer (p. 32, lines 26-29; p. 37, lines 27-30). The specification discloses that human PD2 is overexpressed in pancreatic cancer and is involved in the development of pancreatic cancer (Example I, p. 45; Example III, p. 53).

One cannot extrapolate the diclosureof the specification to the scope of the claims because the specification does not provide guidance or examples for detecting any other proteins other than a PD2 protein consisting of SEQ ID NO:2 or fragments thereof. Given the disclosure of the specification, one of skill in the art would not know how to detect fragments of a protein comprising SEQ ID NO:2 because the fragments could consists of or comprise sequences other than that found in SEQ ID NO:2.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be reasonably predicted that a PD2 protein having the sequence of SEQ ID NO:2 or a fragment thereof would be detected as broadly claimed and contemplated. Therefore, in view of the novel nature of the invention, the breadth of the claims, lack of guidance in the specification, and the absence of working examples, it would require undue experimentation for one skilled in the art to practice the invention as broadly claimed.

9. All other rejections recited in the Office Action mailed October 25, 2005 are hereby withdrawn.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER